

Remarks

Claim 1 is pending and under consideration. Claims 2, 7, 12, 15-17, 28 and 43 are withdrawn from consideration. Claims 3-6, 8-11, 13-14, 18-27, 29-42 and 44-59 are canceled. Claim 1 is amended. Support for the amending language may be found in the specification at paragraphs 0090 and 0091 of the published version of this application. No new matter is added. Reconsideration is requested.

Claim 1 has been rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. Applicants respectfully submit that the presently claimed invention meets the requirement of 35 U.S.C. 112, first paragraph.

Applicants respectfully submit that Claim 1 as presently amended specifically requires an amino acid sequence encoded by the specific nucleotide sequence set forth in SEQ ID NO:1, and having phosphatase activity. The claim provides specific structural and functional limitations for one of skill in the art. Applicants are not claiming the use of any polypeptide, they are claiming only those polypeptides that have a specific sequence and function.

An analysis of the law supports the patentability of the presently claimed invention with respect to written description and enablement. The written description requirement of 35 U.S.C. § 112, first paragraph, does not require a description of the complete structure of every species within a chemical genus. See *Utter v. Hiraga*, 845 F.2d 993, 998, 6 USPQ2d 1709, 1714 (Fed. Cir. 1988) ("A specification may, within the meaning of 35 U.S.C. § 112, ¶ 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses."). The Federal Circuit has held that "[a] description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court has also held that the complete structure of a claimed DNA is not necessarily required. The court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.'" *Enzo*

Biochem, Inc. v. Gen-Probe Inc., 296 F.3d 1316, 1324, 63 USPQ2d 1609, 1613 (Fed. Cir. 2002) (emphasis omitted, alterations in original).

The instant claims are directed to the use of polypeptides, not DNA as in Lilly and Enzo, but the same standard applies. See University of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 925, 69 USPQ2d 1886, 1893 (Fed. Cir. 2004) ("We agree with Rochester that Fiers, Lilly, and Enzo differ from this case in that they all related to genetic material whereas this case does not, but we find that distinction to be unhelpful to Rochester's position. It is irrelevant; the statute applies to all types of inventions. We see no reason for the rule to be any different when non-genetic materials are at issue.").

Each of the genera of polypeptides rejected by the examiner are described in the specification sufficiently to meet the standard set out in Enzo. The specification provides the complete structure of the polypeptides, in that the complete sequence of SEQ ID NO:1 and SEQ ID NO:2 are described and the claimed fragments are merely subsequences of the whole.

With respect to the claimed sequences, the Lilly court held that a genus could be described via "recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." 119 F.3d at 1568, 43 USPQ2d at 1406. The Enzo court held that such a description could take the form of "complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." 296 F.3d at 1324, 63 USPQ2d at 1613.

In this case, the complete structure of SEQ ID NO:1 or SEQ ID NO:2 has been described, and the polypeptides of the claimed genus fall within this structure. Thus, the structural features that are common to the genus make up the structure set forth in Claim 1.

Applicants respectfully submit that Claim 1 meets the requirements for 35 U.S.C. 112, first paragraph, written description.

Claim 1 has been rejected under 35 U.S.C. 102(b) as anticipated by Plowman et al. (WO 01/12819A2).

The presently pending claims have been amended to recite determining the effects of the candidate biologically active agent on liver or colon cancer. The association of liver or colon cancer with the phosphatase of Claim 1 is not taught or suggested by the prior art.

The Office Action refers to pages 6, 8 and 27 of the cited art. Applicants respectfully submit that the cited sections do not teach or suggest the present invention. Page 6 of Plowman *et al.* relates to "administering to a patient an agent that modulates activity of a phosphatase having an amino acid according to the present invention", but does not teach a screening method that determine the effects of the candidate biologically active agent on liver or colon cancer.

Page 8 of the reference states that "modulators or agents that are capable of regulating their activities, either in vivo or in vitro, may be identified and used in the treatment of the given diseased conditions", but does not teach a screening method that determine the effects of the candidate biologically active agent on liver or colon cancer.

Page 27 of the reference states that:

In another aspect, the invention provides an assay to identify substances that modulate the activity of a polypeptide, preferably a phosphatase, comprising the steps of

(a) contacting at least one phosphatase having the amino acid sequence set forth in at least one of the respective numbered amino acid residues as set forth in any Figure;

(b) measuring an activity of the phosphatase; and

(c) determining whether the test substance modulates the activity of the phosphatase.

however the cited reference does not teach a screening method that determine the effects of the candidate biologically active agent on liver or colon cancer, or the specific association of MKPX with colon and liver cancer.

In view of the above amendments and remarks, withdrawal of the rejection is requested.

Conclusion

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number KINE-040.

Respectfully submitted,

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